

REMARKS / ARGUMENTS

Claims 1, 5-16 and 29-30 are pending and stand rejected. By the foregoing amendment, the applicants have amended claim 1. Claims 32-35 are new. No new matter is added by the amendments. Support for the amendments are found in the specification as filed, for example on page 9, lines 1-12 and 20-21. Reconsideration and allowance are respectfully requested.

On page 3 of the Office Action the Examiner rejected claims 1, 5-16 and 29-30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The applicants respectfully traverse the rejection. The Examiner alleged the claim limitation “greater than 1.4 to about 10%” is considered new matter. The applicants submit the claimed range does not have to be explicitly taught in the specification. Rather, the Examiner should take into account which ranges a skilled artisan would consider inherently supported by the discussion in the original disclosure. MPEP § 2163.05(III) and *In re Wertheim*, 541 F.2d 257 (CCPA 1976). The entire range, *i.e.*, greater than 1.4 to about 10%, is described in the specification and thus is not new matter. The claimed range complies with the written description requirement and is allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

On page 4 the Examiner rejected claims 1, 5-16 and 29-30 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “having enhanced stability” in claim 1. The applicants have overcome the rejection by the foregoing amendment to claim 1. Amended claim 1 is definite. Accordingly, the applicants request the Examiner withdraw the rejection.

On page 6 the Examiner rejected claims 1, 5-16 and 29-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Pat. No. 6,991,816 (Esperester et al.) in view of Struengmann (U.S. 6,284,269) in view of Mathowitz (1999) in view of Esperester et al. (WO 01/28363) in view of Abramovici et al. (U.S. 6,303,626) in view of Saslawski et al. (U.S. 6,426,087). The applicants respectfully traverse the rejection. The Examiner did not find persuasive the previously submitted declaration (September 25, 2008). The Examiner submitted the data presented in the declaration does not provide evidence of an unexpected result and the result that “the presence of anhydrous colloidal silica results in a tablet which disintegrates less-readily than a tablet which is not dried in the presence of anhydrous colloidal silica” is expected. The applicants disagree and note the results from the submitted data are unexpectedly superior. Superior stability occurred in the instantly claimed

tablets where the colloidal, anhydrous silica was added to the red vine leaf extract during the spray drying process. Adding colloidal anhydrous silica during the step of drying of the red vine leaf extract gave from 2 to 4-5X better stability. Thus the claimed tablets are superior over any tablet that could be made by a process according to the combination of the references. These results are surprising and unexpected. No skilled artisan would have a reasonable expectation of such results. The Examiner points to nothing in the art that would create an expectation of success for the product made by the process of claim 1. Applicants submit the Examiner has failed to show why the claimed invention would have been obvious.

On page 26, the Examiner alleged that “Esperester already disclosed that the aqueous red vine leaf extract was advantageously dried in the presence of a carrier such as colloidal anhydrous silica”. The applicants note that both the ‘816 patent and the ‘363 reference (the two instantly cited Esperester references) disclose that “carriers or excipients may be added during drying to facilitate further processing of the extract [and] . . . may be silicon dioxide”, however, neither reference discloses any advantageous or unexpected effect of colloidal anhydrous silica or silicon dioxide (col. 3, lines 42-45 of the ‘816 patent, page 4, line 33 to page 5, line 2 of the ‘363 reference).

On page 26, the Examiner alleged that “the test parameters were not kept constant between the two tablets”. The applicants submit that a skilled artisan would reasonably expect that the test parameters that the Examiner points to as not being kept constant (i.e., the lack of crospovidone in formulation I versus 18 mg crospovidone in formulation II, and especially 4.0 mg in formulation I versus 6.0 mg in formulation II of colloidal anhydrous silica) would result in some phenotypic difference between the two formulations, but the skilled artisan would not reasonably expect the differences to result in the surprising and unexpected result as disclosed in the declaration.

On page 26, the Examiner alleged that “varying the amounts and process in manufacturing a tablet is expected to have a bearing on its overall physical nature as clearly indicated by the prior art”. Again, a skilled artisan would reasonably expect some differences to occur due to the varying amounts and process, however, a skilled artisan would not reasonably expect the surprising and unexpected increase in stability as disclosed in the declaration.

In light of the above discussion, the applicants submit the superior effects of the claimed amounts would not be have been contemplated by the skilled artisan viewing the cited prior art references. Therefore, the references do not result in the claimed invention. Thus, claim 1 is not obvious over the '816 patent in view of Struengmann in view of Mathowitz in view of the '363 reference in view of Abramovici in view of Saslawski, and is therefore allowable. Claims 5-16 and 29-30 which depend from claim 1 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

On page 12 the Examiner rejected claims 1, 5-16 and 29-30 under 35 U.S.C. § 103(a) as being unpatentable over Esperester et al. (WO 01/28363) in view of Bilgrami et al. (1993) in view of Struengmann in view of Mathiowitz in view of Saslawski et al. in view of Abramovici et al. and in view of Lieberman, H., Ed. et al. (1990). The applicants respectfully traverse the rejection. For similar reasons discussed above, the combination of the references would not result in the claimed invention. The applicants submit the superior effects of the claimed amounts would not be have been contemplated by the skilled artisan viewing the cited prior art references. Therefore, the references do not result in the claimed invention. Thus, claim 1 is not obvious over the '363 reference in view of Bilgrami in view of Struengmann in view of Mathiowitz in view of Saslawski in view of Abramovici and in view of Lieberman, H., and is therefore allowable. Claims 5-16 and 29-30 which depend from claim 1 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

Applicants submit that all claims pending in the patent application are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

Respectfully submitted,

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s/Timothy X. Gibson/
Timothy X. Gibson, Reg. # 40,618
Attorney for Applicant

Gibson & Dernier LLP
900 Route 9 North
Woodbridge, NJ 07095
Tel: (732) 634-7634
Fax: (732) 634-6887

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877
Tel: (203) 798-9988